

IN THE UNITED STATES DISTRICT COURT  
IN AND FOR THE DISTRICT OF DELAWARE

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THE JOHNS HOPKINS UNIVERSITY, : CIVIL ACTION  
A Maryland Corporation, :  
BAXTER HEALTHCARE CORPORATION, :  
A Delaware Corporation, :  
and BECTON DICKINSON AND :  
COMPANY, a New Jersey :  
Corporation, :  
Plaintiffs :  
v. :  
CELLPRO, A Delaware :  
Corporation, :  
Defendant : NO. 94-105 (RRM)

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Wilmington, Delaware  
Wednesday, April 30, 1997  
10:30 o'clock, a.m.

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BEFORE: HONORABLE RODERICK R. MCKELVIE, U.S.D.C.J.

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APPEARANCES:

POTTER, ANDERSON & CORROON  
BY: WILLIAM J. MARSDEN, JR., ESQ.

Counsel for Plaintiffs

Leonard A. Dibbs and  
Valerie J. Gunning,  
Official Court Reporters

<p>1 APPEARANCES (Continued):  2  3 FOLEY, BOAG &amp; ELIOT  4 BY: DONALD R. KUHL, ESQ. AND  5 PETER B. ELLIS, ESQ.  (Boston, Massachusetts)  6  7 -and-  8  9 ROBERT M. HALLERBECK, ESQ.,  Associate General Counsel  Becton Dickinson &amp; Company  10  11 -and-  12  13 FREDERICK S. SAVAGE, ESQ.,  Associate General Counsel  Office of the Vice President and General Counsel  Johns Hopkins University  14  15 Counsel for Plaintiff Becton Dickinson  and Company  16  17 COWBOY, BOUL, LODGE &amp; EVTS  BY: GERALD H. O'ROURKE, ESQ. AND  W. RICHARD POWERS, ESQ.  18  19 -and-  20  21 LYON &amp; LYON  BY: COO A. BLOOMBERG, ESQ.,  JEROLD B. REILLY, ESQ. and  DAVID S. CHAPMAN, ESQ.  (Los Angeles, California)  22  23 Counsel for Defendant CellPro  24  25</p>	Page 2	<p>1 THE COURT: Actually, I was going to do  2 the opposite.  3 MR. WARE: You want to hear the whole thing?  4 THE COURT: No. I thought I'd pick a couple  5 just to talk about where we are with them.  6 I know that the subject of the injunction is  7 going to be the meat of any argument we have today.  8 Let's see if we can clear some of the other  9 issues up first.  10 MR. WARE: All right.  11 THE COURT: And then come back.  12 But people won't leave today without getting  13 a chance to walk through all of the issues on the  14 injunction.  15 But let's talk about - I guess we've got  16 the marking defense. We've got Beverly documents. We've  17 got misuse.  18 Why don't we talk about misuse for a minute?  19 Who wants to talk about that defense and where it is?  20 MR. BLOOMBERG: I'm happy to address that,  21 your Honor.  22 THE COURT: Good. Okay.  23 MR. BLOOMBERG: As we indicated in our brief  24 with respect to misuse, in order for judgment to be final,  25 a claim must be fully adjudicated. And while the claims</p>
<p>1  2 PROCEEDINGS  3  4 (Proceedings commenced at 10:30 a.m.)  5  6 THE COURT: Okay. We're ready to get  7 started.  8 MR. WARE: May I begin, your Honor?  9 THE COURT: Sure.  10 A few final papers slipped through last  11 night that I have not yet read, but you should assume  12 I've read everything.  13 MR. WARE: We always do, your Honor.  14 THE COURT: I remember walking past some of  15 them last night.  16 MR. WARE: We like to think in the middle of  17 the night there's a reason why we're there.  18 THE COURT: I thought what we'd do is a  19 variation on pick a topic.  20 MR. WARE: The suggestion that I had was that  21 we begin generally the subject of the injunction, where  22 there are, I think, the most issues to discuss, and that  23 we perhaps address some of the issues separately and  24 both sides be heard on them, and then move on to  25 another point. There are a number of discrete issues.</p>	Page 3	<p>1 of the patents here involved have been found to be valid  2 and infringed, nevertheless, there's an issue as to  3 whether or not those claims are unenforceable because of  4 misuse.  5 Under 35 United States Code 271, Subpart (d),  6 Subpart (5), the statute sets out that misuse or an  7 illegal extension of a patent right by reason of  8 conditioning a license of rights to a patent on the  9 acquisition of rights in another patent where the patent  10 owner has market power in the relevant market is a  11 defense.  12 And that's the situation here. Almost a  13 textbook example of misuse is contained in Defendant's  14 Exhibit No. 709.  15 Your Honor will recall that that is a letter  16 dated April 15th, 1992 from Baxter, where they indicated  17 that they were no longer interested in granting a  18 license with a running royalty rate and a lump-sum  19 payment, but wanted from CellPro exclusive rights to  20 CellPro's patents in Europe and Japan and nonexclusive  21 rights in North America.  22 THE COURT: How do you propose to resolve  23 this issue?  24 MR. BLOOMBERG: I would propose that discovery  25 be taken on the matter and that it be tried before a jury.</p>

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<p>1        THE COURT: Mr. Ware? I've read the briefing 2 on the topic.</p> <p>3        MR. WARE: Well, we have not actually briefed 4 the substance of the topic. I think there was brief 5 comment on it in the injunction brief that we filed.</p> <p>6        As far as where this is, the patent misuse 7 issue was, in fact, stayed by agreement of the parties, 8 and what we would propose to do, if CellPro is unwilling 9 to withdraw this defense, is we would propose to set a 10 briefing schedule and we will brief it. We think it can 11 very easily be disposed of as a matter of law.</p> <p>12       THE COURT: You mean brief a summary 13 judgment?</p> <p>14       MR. WARE: Yes. A summary judgment briefing 15 schedule.</p> <p>16       THE COURT: The parties agree to defer the 17 presentation of the defense.</p> <p>18       Was that in response to my comment that I 19 would otherwise shoot it into outer space, or what does 20 the agreement require?</p> <p>21       MR. WARE: The original agreement was, I 22 think – the original agreement was crafted at the very 23 beginning of the case, probably even before there had 24 been hearings before the Court. And at that time I 25 think that the thinking was probably on the part of</p>	<p>1 issue that we truly believe could not survive a Rule 11 2 motion.</p> <p>3        THE COURT: Well, are you in a position – I 4 mean, do you know what you're moving for summary judgment 5 on?</p> <p>6        MR. WARE: Yes.</p> <p>7        THE COURT: What the facts are that they'll 8 be relying on?</p> <p>9        MR. WARE: Yes. I think that there are 10 several points here that need to be kept in mind. 11       In the first place, as I understand it, and 12 based upon what Mr. Bloomberg just said, in addition to 13 the hand-guards-type defense, which I assume Mr. 14 Bloomberg would agree, in light of the Court's rulings, 15 doesn't survive as a patent misuse defense, but, in 16 addition, this argument – the patent-misuse argument 17 seems to be based entirely on an April 15th letter from 18 Baxter to CellPro, which the Court will recall from the 19 trial, in which Baxter simply made a proposal that the 20 license include distribution of CellPro's products in 21 Europe.</p> <p>22       And the statement that Mr. Bloomberg just 23 made about conditioning anything on rights under CellPro 24 patents is nowhere contained in that letter and it has 25 never been suggested in five years of litigation until</p>
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<p>1 both parties that, to the extent that the parties can 2 avoid the unnecessary cost of antitrust-type discovery 3 and proceed with the patents, that they ought to do so.</p> <p>4        Moreover, at least at that time, as I recall 5 it, the patent misuse defense was, in substance, a 6 hand-guards-type defense. And so, therefore, if the 7 patents were found to be valid, there would be nothing 8 left of the defense. And that's a further reason that 9 we contend now that there is no justification for going 10 forward with this defense in light of the Court's 11 findings.</p> <p>12       But I think that what was contemplated at the 13 time, or at least as the stay was written, the entire 14 patent case was to be resolved and disposed of before 15 dealing with the patent misuse issue, since CellPro has 16 now raised an objection to entry of permanent – entry 17 of a permanent injunction as part of a final judgment, 18 because technically its patent misuse is pending.</p> <p>19       We would like to dispose of the patent misuse 20 defense so that there will be no question about the 21 Court's entry of final judgment, including a permanent 22 injunction.</p> <p>23       THE COURT: All right.</p> <p>24       MR. WARE: We certainly do not think it would 25 be appropriate to open up antitrust-like discovery on an</p>	<p>1 this day that that had anything to do with it.</p> <p>2        But, very briefly, we find no legal support 3 for the proposition that a licensee, such as Baxter, 4 cannot ask for distribution as part of a proposal for 5 the – that is, distribution of the licensed product 6 itself, a product that an infringer could not sell in 7 the United States or could not export under any 8 circumstances.</p> <p>9        Secondly, as the Court is aware, this 10 proposal never came to fruition and defenses such as 11 this do not come up when the other party rejects the 12 proposal. And the parties move on in their negotiation.</p> <p>13       One does not go back and reconstruct 14 negotiations to find one proposal made on one day that 15 was not accepted and turn that into a patent misuse 16 defense. This is a proposal that never happened.</p> <p>17       And, thirdly, as the Court is aware from 18 the trial, on July 15th, 1992, Baxter reiterated its 19 earlier offer of a pure patent license. That is, it 20 said, essentially, We thought you were interested in 21 talking to us about distribution, which is certainly 22 supported by the evidence in this case, but if you're 23 not interested in talking to us about distribution, 24 fine. You can have the license that we offered in the 25 first place.</p>

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1 And the law is absolutely clear that, even  
 2 if there were misuse, that a purging of that misuse  
 3 takes away the defense entirely.  
 4 So what we're talking about is a three-month  
 5 period in April that was -- certainly, if there was any  
 6 misuse, was purged by July, when CellPro was given an  
 7 opportunity on the same terms that were offered before  
 8 to take a pure patent license. CellPro declined.

9 There is no patent misuse under those  
 10 circumstances, and that's a purely legal conclusion that  
 11 the Court can draw based on undisputed facts.

12 THE COURT: And what discovery would you want  
 13 to take?

14 MR. BLOOMBERG: We would want discovery with  
 15 respect to the preparation of this April 15th letter. The  
 16 authorship, the review of the letter, approval of the  
 17 letter, comments with respect to the letter, documents  
 18 regarding business plans or financial plans with respect  
 19 to the countries affected by the conditioning of the  
 20 license.

21 As to the issue raised by Mr. Ware regarding  
 22 this so-called purge letter, which I believe is  
 23 Defendant's Trial Exhibit No. 637, I think the date is  
 24 July 22nd, rather than July 15th, 1992.

25 Your Honor will recall that there was a --

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1 MR. BLOOMBERG: Yes. To the extent Mr. Ware  
 2 wants to raise an issue of this purge letter, it seems to  
 3 me it would be appropriate to find out if those terms  
 4 were really made available to CellPro. And as I say, Mr.  
 5 Murdock's testimony is that when CellPro and Baxter met,  
 6 they were not.

7 THE COURT: And so when we talk about  
 8 discovery, I had in mind discovery relating to those  
 9 communications, as opposed to getting in and rolling  
 10 around inside Baxter as to these matters. What  
 11 additional discovery do you need with regard to those  
 12 two communications?

13 MR. BLOOMBERG: Beyond what I've already  
 14 identified?

15 THE COURT: Right.

16 MR. BLOOMBERG: The only other issues that I  
 17 think discovery would bear on this particular misuse would  
 18 relate to the market power and the relevant market as  
 19 conditions of 35 United States Code 271(d)(5).

20 THE COURT: So have you deposed the people  
 21 who -- the author of the letter, for example?

22 MR. BLOOMBERG: We have taken his deposition.

23 THE COURT: Have you deposed people that  
 24 participated in the meetings?

25 MR. BLOOMBERG: No, we have not.

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1 shortly thereafter, there was a meeting between Baxter  
 2 and CellPro representatives, and Mr. Murdock has testified  
 3 in court that at that meeting the terms of the so-called  
 4 purge letter were not made available to CellPro, so we  
 5 would want discovery with respect to that meeting as well.

6 I think there would also --

7 THE COURT: It sounds like what Mr. Ware is  
 8 saying is it's almost a 12(b)(6) motion. And that is you  
 9 can identify the letter and say that's the basis for your  
 10 claim. But you can't identify any other facts that would  
 11 show misuse that would be communications to your client.

12 In other words, I know you want to go  
 13 upstream from the letter, but how would that be relevant  
 14 to establishing a claim if you can't show those matters  
 15 were communicated to your client?

16 MR. BLOOMBERG: I think there were actually  
 17 two communications, your Honor. There was a meeting, I  
 18 believe, in Southern California at a Baxter facility  
 19 where the same representations were made orally, and then,  
 20 as I understand it, from Mr. Murdock's testimony, the  
 21 substance of that correspondence was confirmed in this  
 22 letter.

23 THE COURT: And so wouldn't discovery, at  
 24 least in the first instance, go to what was communicated  
 25 to CellPro and what was said in response to that?

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1 MR. WARE: Your Honor, just a couple points.

2 First of all, we would be prepared by the end  
 3 of next week to file a summary judgment brief and it would  
 4 be a proper summary judgment type issue that we would  
 5 argue, and we would like the opportunity to do that  
 6 rather than permit CellPro to start taking discovery on  
 7 market power and everything else that you hear about in  
 8 antitrust cases, which are very time-consuming and  
 9 expensive.

10 There is absolutely no law that exists that  
 11 says someone making a proposal thereby engages in patent  
 12 misuse.

13 And I think we ought to have an opportunity to  
 14 try to have this resolved as a legal matter before going  
 15 into discovery.

16 THE COURT: Okay. Let's pick another topic.  
 17 Documents relating to Beverly.

18 MR. BLOOMBERG: This issue, I think, your  
 19 Honor, relates to dialogue between Dr. Beverly and the  
 20 plaintiffs with respect to our inequitable-conduct claim.

21 THE COURT: Okay.

22 MR. BLOOMBERG: As I understand it, much of  
 23 these documents have been asserted to be work product or  
 24 attorney/client, and we don't think it's appropriate to  
 25 make that claim in connection with a third party.

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1 THE COURT: What's the matter in issue? What  
 2 is it that is still open that these documents are  
 3 relevant to?

4 MR. BLOOMBERG: Well, in view of your Honor's  
 5 ruling on inequitable conduct, I'm not certain that it  
 6 is -- that it remains a viable issue in the case. But  
 7 that was the purpose of our seeking those documents --  
 8 THE COURT: All right.

9 MR. BLOOMBERG: - is they bore on  
 10 inequitable conduct.

11 THE COURT: All right. Let's move to the  
 12 topic of motion for - let's move to the three issues  
 13 together. That is, the motion for injunction, the motion  
 14 for enhanced damages, and the application for an award  
 15 of fees.

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1 THE COURT (continuing): If final judgment  
 2 is going to be deferred until I can deal with this  
 3 question of misuse, what happens to your application for  
 4 an injunction? Do you want a preliminary injunction?  
 5 ---

6 MR. WARE: I think that, since we're all here,  
 7 we'd like to argue it, but I think we would like a  
 8 permanent injunction. And I think it makes more sense,  
 9 because I think the patent misuse issue can be disposed  
 10 of quickly. And I don't see what the advantage is,  
 11 particularly given the stay we've proposed.

12 There is nothing that can't be addressed in  
 13 permanent injunction. Insofar as we have proposed that  
 14 any stay be conditioned on certain payments from  
 15 CellPro, we've asked that those payments be made based  
 16 on sales retroactively to March 12 anyway.

17 So I don't think a brief delay in entering  
 18 the injunction will affect that. And we have generally  
 19 accepted the proposition of a stay on the terms proposed,  
 20 such that, again, I don't think a matter of a couple of  
 21 weeks or so or a few weeks is going to make much  
 22 difference.

23 And I think that we would rather have the --  
 24 if this is going to go to the Federal Circuit, we'd

1 rather have them be reviewing a permanent injunction.  
 2 THE COURT: If I simply enter the order now  
 3 for the injunction, took the word "permanent" out, just  
 4 said order for injunction, partial stay of injunction,  
 5 that would be an appealable order?

6 MR. WARE: I believe so.

7 THE COURT: And the case would then go up,  
 8 presumably go up.

9 MR. WARE: Yes.

10 And under 1291(a), I think. And so I think  
 11 that - I think it would be helpful to anybody reviewing  
 12 the record in this case to have the benefit of the  
 13 Court's further thoughts on some of the issues that  
 14 are before it now.

15 THE COURT: See, that's what I was wondering  
 16 about the relationship of the timing of the injunction  
 17 and whether or not plaintiffs would prefer to defer the  
 18 entry of the injunction until I have a chance to write  
 19 something on the subject of fees and enhanced damages.

20 And I take it that's what you are saying:  
 21 Is you would rather wait until I can get something  
 22 written on that?

23 MR. WARE: Yes. I think we're perhaps  
 24 being presumptuous, but we hope that could be in some  
 25 reasonable time frame. And I do think it would be

1 helpful to the Court of Appeals to have the benefit of  
 2 the Court's written decision.

3 THE COURT: All right.

4 MR. WARE: There's a sort of a procedural  
 5 piece of the attorneys' fee application that we might  
 6 just discuss briefly -

7 THE COURT: Sure.

8 MR. WARE: - because, as we're going  
 9 through some of these items, to get them out of the way.

10 I think the issues are pretty  
 11 straightforward, as far as the Court's authority to  
 12 award fees. And I think that the issue that we seek  
 13 some guidance from the Court on has to do with the  
 14 submissions that the Court wants to see, in terms of  
 15 the backup information. We have provided to the Court  
 16 in the application a detailed breakdown by lawyer, by  
 17 time period of hours. And we have provided the billing  
 18 rates.

19 We have not at this time submitted to the  
 20 Court detailed, daily time reports of lawyers, and we  
 21 have not submitted to the Court at this time actual hard  
 22 copies of individual invoices for transcripts and things  
 23 like that.

24 We have provided the Court a -- subtotals  
 25 based upon an itemization of the types of different

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1 costs that we're seeking. There's no indication in  
 2 the papers submitted by CellPro that there is objection  
 3 in concept to the particular types of expenses that we  
 4 are seeking. And as to the time detail, we have a couple  
 5 of concerns.

6 We have the concern that the time detail  
 7 itself contains information that we regard as  
 8 confidential work product, and we're reluctant to  
 9 provide it to opposing counsel, although we are not in  
 10 the least reluctant to provide it to the Court in  
 11 camera.

12 We also had requested some time ago from  
 13 CellPro the equivalent information from Lyon & Lyon,  
 14 and that was refused. It seems to us that if Lyon --  
 15 if CellPro is proposing to object specifically to the  
 16 number of hours spent in a time period or whatever,  
 17 that we would be entitled to see the time spent by  
 18 their lawyers as well, that that would be at least a  
 19 relevant piece of evidence.

20 It seems to us that CellPro -- from reading  
 21 the opposition brief, that CellPro's objection really is  
 22 not -- does not have anything to do with the time spent  
 23 on the case. The only substantive objection was the  
 24 suggestion that the billing rates ought to be  
 25 Wilmington billing rates, rather than national billing

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1 requesting are considerably -- they're considerably less  
 2 than what the plaintiffs actually paid, they are, we  
 3 believe, considerably less than what CellPro paid to its  
 4 lawyers, that we really just should not have to make that  
 5 information available to CellPro.

6 But that's why we seek guidance.

7 THE COURT: Do you want to say something?

8 MR. BLOOMBERG: Well, I think that in order  
 9 for us to properly evaluate their application, we need to  
 10 see the supporting documentation, which we have not seen.

11 As to Mr. Ware's comments regarding our  
 12 billings, our understanding is that the standard is the  
 13 local fee rates, as opposed to rates in California.

14 As to Mr. Ware's comments that, as to the  
 15 willfulness, we were able to prevent plaintiffs from  
 16 taking discovery based upon attorney/client and work  
 17 product.

18 Your Honor will recall that much of our  
 19 documentation that was clearly work product or  
 20 attorney/client was found to be waived and made  
 21 available to the plaintiffs.

22 THE COURT: I have a couple thoughts.

23 My understanding is that at the moment, with  
 24 the application for fees pending -- and, actually, with  
 25 my invitation to plaintiffs to file the application,

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1 rates.

2 CellPro has refused our request that they  
 3 provide information concerning Lyon and Lyon's billing  
 4 rates. We think that the billing rates are very much  
 5 in line with national firms engaged in the sort of  
 6 practice. But we're a little bit unsure as to what to  
 7 do at this point. We want to give the Court whatever  
 8 information it feels it needs to be able to make -- to  
 9 review the request.

10 And if that sort of detailed daily report is  
 11 something that the Court wants to go through over a  
 12 period of five years, again, we are happy to do it. But  
 13 we do have this concern about disclosure of all of the  
 14 details of every potential witness we ever talked to or  
 15 every issue we looked into or what-have-you.

16 And there was really a parallel situation  
 17 earlier in this case, when we sought discovery from  
 18 Lyon & Lyon with respect to the willfulness issue. And  
 19 we were not permitted to see any of their internal  
 20 records, really for the same reason. They were  
 21 concerned about work product.

22 And so it seems to us that, in light of that,  
 23 and in light of CellPro's refusal to provide the  
 24 information with respect to Lyon and Lyon's time, and in  
 25 view of the fact also that the fees, we think, that we're

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1 that it's on my plate to resolve before the case goes  
 2 up.

3 I'd sort of prefer to find a procedural way  
 4 to send the case up and do a final review of this issue  
 5 if and when it comes back affirmed. But if I cannot do  
 6 that, I cannot do that.

7 There are a couple of advantages to doing it  
 8 that way. One advantage to doing it that way is that at  
 9 that point I think people -- we could have more of an  
 10 open review of the issue of fees and time put in and  
 11 comparison, and we could do it in the context -- I don't  
 12 know whether the Federal Circuit has a separate provision  
 13 for an award of fees or whether they remand it to the  
 14 District Court to take care of that issue, but the costs  
 15 and fees on appeal can then be added in with less concern.  
 16 And I can even refer to a Master or somebody like that to  
 17 review it.

18 If I cannot -- if I cannot put it off, and  
 19 if plaintiffs don't want me to put it off until the case  
 20 goes up, then what I'm inclined to do is the following:  
 21 I can tell you right now I'll apply a national standard  
 22 to the award for the calculation of fees and costs, as  
 23 opposed to a local Delaware standard, in part because I  
 24 don't want to restrain the national Bar with the high  
 25 Delaware rates that are billed.

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1        Second, what I will do is the following:  
 2 I'll take the information that the plaintiffs have given  
 3 me as their best shot. I will review it, to see whether  
 4 I think it is adequate. If I have any particular  
 5 questions, I will let people know promptly in time to  
 6 get information back to me.

7        CellPro can review what it is that the  
 8 plaintiffs have submitted and raise specific questions,  
 9 if they want to, by category, by topic.

10       But if there is a specific review, I am going  
 11 to need to look at what is reasonable. And one way of  
 12 looking at what's reasonable is looking at what CellPro  
 13 did, in terms of their defense. That is, it was  
 14 unreasonable to spend eight hours to prepare for that  
 15 deposition. I'll look and see what the records of  
 16 Lyon & Lyon show.

17       So it's going to have to be an issue where,  
 18 if there's a challenge to the fees, it needs to be  
 19 identified, either by CellPro or by me in my review.

20       And I know that there are lots of categories  
 21 of areas where there's reasonable arguments that this  
 22 shouldn't be included, this should be included. And I  
 23 am open to hear argument on it. But if it's going to  
 24 get into the files, I will find a way to get into the  
 25 files to get it satisfied or find a way to articulate to

1 look at it and see?  
 2        MR. WARE: Why don't we look at it and why  
 3 don't we perhaps communicate back to the Court based on  
 4 the comments the Court has made what we think makes  
 5 sense to do at this point.

6        THE COURT: When you look, you'll find a  
 7 wonderful opinion by the Third Circuit on the types of  
 8 attorneys' fees in civil rights cases that says that  
 9 when you have a civil rights case, and you settle it, and  
 10 the defendant gives to the -- gets from the plaintiff a  
 11 general release of all claims, including claims relating  
 12 to attorneys' fees, that's not a waiver of attorneys'  
 13 fees under the Civil Rights Law.

14       MR. WARE: I think I remember that case.

15       THE COURT: I don't think many people in the  
 16 Bar know that, but the plaintiffs' bar likes to get a  
 17 case, get all the money they can, settle, say they waive  
 18 our claim for fees and then fees for fees under the  
 19 Civil Rights Law.

20       Not many Circuit Judges write opinions that  
 21 bury those type of problems in the law, but we had a few  
 22 in the Third Circuit that did for a while.

23       In any event, look at it. See what you want  
 24 to do. I'm going to leave the bench today and assume  
 25 that I have on my plate the subject of an application

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1 the Appeals Court, to the extent that I award fees, what  
 2 I did and why I did it.

3        MR. WARE: Would there be any merit to the  
 4 idea of addressing, or making a determination about  
 5 whether fees are to be awarded and under what statutes  
 6 without actually calculating them and having it go up  
 7 that way?

8        THE COURT: That's why God invented lawyers.  
 9 Judges don't know the answer to anything. They just  
 10 pick what you say, until Exxon came along, and then I  
 11 had to come up with my own independent view. I would  
 12 have thought there are mechanisms to do that. That is,  
 13 I intend to award.

14       On the other hand, if, was the Appeals Court,  
 15 I might say, Look -- well, if you go look at the world  
 16 about what happens with fee applications, my general  
 17 sense is that what happens is the case gets tried.  
 18 Party makes an application for fees. The Trial Court  
 19 puts it in its pocket. It goes up on appeal. It gets  
 20 affirmed. If it gets affirmed, it comes back and the  
 21 Trial Court resolves all of the issues about fees. Our  
 22 local rule has a specific provision about the time  
 23 period for filing fee applications, and I thought it  
 24 was within a certain number of days after the decision  
 25 came down from the Appeals Court. But why don't you

1 for fees and costs and the subject of enhanced damages  
 2 and I'll begin working on it. I'll be applying the  
 3 standards that I would otherwise apply to it.

4        To the extent that CellPro raises damages  
 5 with regard -- awarding fees for appropriateness of  
 6 certain matters, I looked at the briefing. I didn't  
 7 notice in the briefing there were many issues that I  
 8 thought raised particular factual problems, but I'll  
 9 look. And if CellPro wants to go back and look at it  
 10 again, that's fine with me. I am interested in getting  
 11 the right result here.

12       But I have in the past, and frequently,  
 13 when a party objects to a rate, I say, fine. So tell  
 14 me your rate. Then I have some indication of  
 15 reasonable -- all right. So that's where we are on  
 16 that.

17       And I raise all that in part because I  
 18 thought, one, and I'm sure plaintiffs have thought  
 19 about this, one way to go would be to simply enter  
 20 the injunction, and let people go up to the Federal  
 21 Circuit in the context of a decision that basically  
 22 says, this implements the jury's decision.

23       We've got some other issues to take care of  
 24 here, but there's no reason to delay the case going up.  
 25 But if the plaintiffs want me to write out on the issue

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1 of enhanced damages and the award of attorneys' fees,  
 2 I'll do that, too. I will assume, unless you apply  
 3 otherwise --

4 MR. WARE: That's our present thinking.  
 5 Yes.

6 THE COURT: Okay.

7 On the subject of the terms of the proposed  
 8 permanent injunction, I have read the briefing. I  
 9 think I understand the positions of the parties. I  
 10 think they are pretty clear. I am happy to hear  
 11 argument, if people want to supplement what they've  
 12 already said in the briefing. But I don't know that  
 13 I had any particular questions. I've just got some  
 14 reading to do, to solve certain questions I've got.

15 MR. WARE: Let me just ponder that for a  
 16 minute.

17 (Pause while Mr. Ware and Mr. Ellis  
 18 conferred.)

19 MR. WARE: What we are thinking about, your  
 20 Honor, would be just highlighting a few of the issues  
 21 that are maybe most highly contested, and making sure  
 22 that we have anticipated any questions that the Court  
 23 might have, and certainly responding to anything further  
 24 that CellPro has to say on the point.

25 MR. BLOOMBERG: With your Honor's permission,

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1 injunction that I might comment on briefly is the  
 2 proposed two-year injunction with respect to sales in  
 3 Europe. And there, of course, is a stay of that. But  
 4 I think that the emphasis really is on a couple of  
 5 points. One is that this is a remedy for infringement  
 6 in the United States, and it is really not very different  
 7 from the very typical sort of trade secret injunction,  
 8 which typically are worldwide, when somebody has  
 9 misappropriated a trade secret, and thereby acquired for  
 10 themselves a head start in a market. And their having  
 11 done so is very destructive of the marketplace for the  
 12 licensed patent -- for the patent-holder or the  
 13 licensee.

14 And so it is very common to enter that sort  
 15 of injunction. That's what that's about.

16 In terms of the mandatory injunction, the  
 17 repatriation of the 12.8 hybridoma we think is vital.

18 We have addressed in the papers the  
 19 conclusion that CellPro clearly did infringe in the  
 20 United States through its ongoing use of the 12.8  
 21 hybridoma after the issuance of the patent.

22 This is a situation where, by CellPro's  
 23 attempt to evade the United States patent laws by  
 24 sending hybridoma cells to Canada in the midst of  
 25 litigation, the patent-holders have been deprived of

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1 Mr. Riley would argue the injunction on behalf of CellPro.  
 2 THE COURT: Fine.

3 MR. RILEY: If I may stay here until he's  
 4 finished, your Honor. I might want to take notes.

5 THE COURT: Whatever you want.

6 MR. WARE: Okay. As the Court is aware,  
 7 the injunction is structured to include essentially four  
 8 elements, one being a prohibitory injunction, one being  
 9 a mandatory injunction, the third being a temporary stay,  
 10 and the fourth, which I guess is part of the temporary  
 11 stay, relates to calculation of payments of incremental  
 12 profit during the stay.

13 I don't think I need to say very much about  
 14 the prohibitory injunction, other than to emphasize that  
 15 it is key we believe that there be one. That the end  
 16 point must be an injunction here. And, in the absence  
 17 of an injunction, the value of patent rights would be  
 18 very greatly diminished and would become very difficult  
 19 for inventors and non-profit institutions, such as Johns  
 20 Hopkins University, to be able to license out their  
 21 patents. And there certainly is no exception for  
 22 infringement that happens to involve medical products.  
 23 There are injunctions entered all the time against  
 24 infringing medical devices.

25 The other aspect of the prohibitory

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1 rights that they would otherwise have had.  
 2 They would have had the right, upon a finding  
 3 of infringement, to request destruction of the  
 4 infringing hybridoma, in which case it could not have  
 5 been sent to Canada.

6 They could have requested, and the Court  
 7 would properly have entered an injunction against  
 8 exporting the infringing hybridoma.

9 So they were deprived of those rights. And  
 10 to remedy that, the Court must require them to bring it  
 11 back to the United States.

12 It's really no different than a party that  
 13 sends out or smuggles out of the United States stolen  
 14 goods. They are still within the possession and  
 15 control -- not possession, but control of the infringer,  
 16 and they ought to be brought back.

17 We even know, by reason of the filings that  
 18 have been made most recently, that CellPro itself  
 19 recognized that the operation in Canada was really a  
 20 sham and that, as soon as the jury verdict came down in  
 21 the first trial, CellPro ceased manufacturing abroad.  
 22 They had no real intention of manufacturing there.

23 The mandatory injunction also includes a  
 24 destruction order. I think, ultimately, the plaintiffs  
 25 are entitled to it.

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1       The plaintiffs should not be in a position  
 2 where they have to police all of the activities of  
 3 CellPro regarding 12.8. It is very easy to clone  
 4 hybridoma cells and ship them out of the United States.  
 5 We shouldn't have to be guarding that. We shouldn't have  
 6 to learn that at some point in the future that, all of a  
 7 sudden, people are being supplied with 12.8 antibody from  
 8 the Cayman Islands or somewhere else.

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2       THE COURT: What's the evidentiary record on  
 3 the shipping of the 12.8 hybridoma to Canada?

4       MR. WARE: There had been summary judgment  
 5 briefing in 1985 on the issue, and there was deposition  
 6 testimony of a Mr. Bordinaro from CellPro that had been  
 7 submitted to the Court at the time and Mr. Bordinaro,  
 8 in fact, submitted a declaration.

9       There are certain facts that are undisputed,  
 10 including the fact that it was in 1993 that CellPro  
 11 shipped the hybridoma to Canada. And the various facts  
 12 on which we -- the various facts we have pointed to in  
 13 terms of CellPro's maintenance and use of the 12.8  
 14 antibody in the United States after the patent issued  
 15 and before the cells were shipped to Canada are also  
 16 undisputed. That is, they come out of Mr. Bordinaro's  
 17 deposition.

18       So that's really the basis of the  
 19 evidentiary record, then.

20       Mr. Bordinaro acknowledged that the -- that  
 21 although CellPro first cloned the cells that they  
 22 obtained from the Fred Hutchinson Cancer Research  
 23 Institute in -- I believe it's early 1990, that the  
 24 cell bank that they made out of those cells was not  
 25 even released for use until -- I believe it was in '91

1       MR. WARE (Continuing): And so we think that  
 2 that's an appropriate order ultimately.

4       However, in view of the stay that we seek,  
 5 that will not come to pass in the near term.

6       What I might suggest, because I think there  
 7 are enough differences here that -- I might suggest that  
 8 we hear from Mr. Reilly on those aspects of the  
 9 injunction before turning to the stay, because otherwise,  
 10 I will have kind of a long presentation here.

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1       or '92. Maybe even in '93, but sometime after the  
 2 patent issued, because there's a whole series of steps  
 3 of quality-control testing and things that have to be  
 4 done before you can release it.

5       But, again, it's based on the evidence --  
 6 that -- both documentary and deposition testimony of  
 7 Mr. Bordinaro.

8       THE COURT: All right.

9       MR. REILLY: Good morning, your Honor.

10       THE COURT: Good morning.

11       MR. REILLY: Let me start with the  
 12 injunctions, request for repatriation of hybridoma in  
 13 Canada. This was summary judgment briefed in 1995. I  
 14 think what happened is the trial crept up on us and it  
 15 was never argued. It's briefed a lot more thoroughly in  
 16 1995. I would refer the Court to DI-158, 159, 249 and  
 17 269 was the briefing on that.

18       We have a rather different interpretation of  
 19 Mr. Bordinaro's testimony. The facts, as I understand  
 20 them, is that -- and this much is certainly undisputed --  
 21 the 12.8 antibody was discovered before the '204 patent  
 22 issued.

23       There were six vials shipped to Canada.  
 24 The six vials shipped to Canada were frozen. They  
 25 remained in a frozen state, unaltered and undiluted.

<p>1 with, except to keep them cold so they would not die, 2 until a time in 1993, when they were sent to Canada. 3 Simply put, CellPro's position is that the 4 hybridoma is not an infringing product because, even if 5 it is within the claims of the patent, the patent 6 didn't issue until subsequently. 7 It's sort of like the parable of the 8 widgets, if I may say, your Honor. If you make a 9 bushel basket full of widgets and you have them there 10 and then one subsequent day I get a patents issued to 11 me that reads on the widgets, they do not become 12 infringing widgets. We know that because Section 271(a) 13 tells us that. He who makes, uses or sells during the -- 14 in the United States during the term of the patent 15 infringes and not otherwise. 16 So a device or a product that is made before 17 a patent issued does not become an infringing product if 18 the patent issues. 19 If you thereafter use it or sell it, those 20 are acts of infringements. 21 But, certainly, you would be perfectly 22 within your legal rights to store your widgets for 17 23 years or until I fail to pay my maintenance fee or 24 something or my patent is declared invalid. 25 Simply storing a product that was made</p>	<p>Page 34</p> <p>1 hybridoma to Canada, the mere fact of storing it in its 2 frozen state before it went to Canada cannot be acts of 3 infringement. 4 There's no act of infringement that has been 5 committed with respect to those six frozen vials in 6 Canada. They were thawed out after and used in Canada, 7 but not in the United States. It's simply our position 8 there has been no act of infringement with respect to 9 those vials. Plaintiffs have called this an evasion of 10 the U.S. patent laws, but it's no more of an evasion 11 than if I moved to Switzerland and lawfully pay my taxes 12 in Switzerland. Once I move out of the country and 13 don't have any activities here that tax is due on, it's 14 certainly not an evasion of the U.S. tax laws. 15 So I think plaintiffs' position just 16 basically violates the principle of territoriality of 17 the patent laws and there's no basis to repatriate that 18 hybridoma. 19 The other thing I should mention is that 20 CellPro does not really own it free and clear. The 21 hybridoma is licensed from the Fred Hutchinson Cancer 22 Center and there's provision in the license agreement 23 that if the -- the license ever terminates, CellPro 24 would have to return any of the remaining stock of 25 the hybridoma to the Fred Hutchinson Cancer Center.</p>
<p>1 before a patent issued does not turn that product into 2 something that infringes. The mere act of keeping it 3 around, and the mere act of shipping it out of the 4 country, are not acts of infringement. And we do cite 5 law on that. 6 If you didn't want to keep your widgets in 7 the United States for 17 years until my patent expired, 8 you could ship them to Canada. And if I had no patent 9 rights in Canada, you could just sell them in Canada, 10 and that would not be an act of infringement. 11 And, again, what tells us that is 271(a), 12 which says that he who, within the term of the patent 13 in the United States, makes, uses or sells, infringes 14 the patent. 15 The case that plaintiffs have cited for the 16 point that mere storage constitutes an infringing act is 17 what I call the howitzer case. It's the Olson case. 18 Very strange case. And I think it's sui generis. It 19 dealt with howitzers. And the Court says the use of 20 howitzers in peacetime is to just sit around and be a 21 deterrent, so their storage is use. 22 The other distinguishing fact about that 23 case is the howitzers were made during the term of the 24 patent. The 12.8 antibody was discovered before the 25 patent issued. So the mere fact of shipping the</p>	<p>Page 35</p> <p>1 The other point I would make, your Honor, 2 is that to actually round up the hybridoma and kill it 3 would be as one clinician said to me when I mentioned 4 this, it would be like killing Einstein. 5 This is not the situation where someone 6 makes a bunch of Rolex watch knock-offs and they call a 7 press conference and hire a steam roller and flatten 8 the watches. 9 A hybridoma, as your Honor well knows, is 10 a unique, living organism. You can never get another 11 one like it as a practical matter. And if it were 12 ordered destroyed then, as a practical matter, neither 13 CellPro nor anyone else could begin using it again when 14 the patent expires or is ultimately found invalid or for 15 any other reason becomes unenforceable. 16 Something made before a patent begins, there 17 ought to at least be a right to store it until the patent 18 term is over. And I think that the law should be clear 19 on that, and that to actually order this hybridoma 20 destroyed really would be a great loss to science and 21 way, way beyond the bounds of, I think, anything that 22 the Court should fairly do, even if there were an act 23 of infringement here, which there hasn't been. 24 THE COURT: During the discovery, was there 25 discovery of documents about the motive that CellPro had</p>

<p>1 and communications that related to the decision to ship 2 the hybridoma to Canada?</p> <p>3 MR. WARE: Well, there was discovery of 4 communications from Lyon &amp; Lyon to CellPro. This was a 5 scheme that was devised by CellPro and its lawyers, and 6 CellPro -</p> <p>7 THE COURT: Were these documents withheld as 8 privileged?</p> <p>9 MR. WARE: They were produced.</p> <p>10 THE COURT: They were produced?</p> <p>11 MR. WARE: Yes.</p> <p>12 THE COURT: And they are in the summary 13 judgment briefing?</p> <p>14 MR. WARE: I don't think so. I don't think 15 so.</p> <p>16 I don't know - well, no, I don't think so.</p> <p>17 THE COURT: Can you provide them?</p> <p>18 MR. WARE: Yes. We can provide them.</p> <p>19 THE COURT: To the extent there are documents 20 that may shed some lights on CellPro's intent at the 21 time, I'd be interested in seeing them.</p> <p>22 MR. WARE: Yes. Now, there was no 23 discovery, that is whether we deposed Mr. Bloomberg, 24 for example, I don't think we went into those. But 25 those documents themselves do exist.</p>	<p>Page 38</p> <p>1 cited in our reply brief. It's called Amgen versus 2 Ellenex (phonetic) that actually does involve frozen 3 cell lines, oddly enough, in Bothel (phonetic), 4 Washington, a different company. The decision was 5 written by Judge Dimmick, who was the original Judge 6 in the declaratory action brought in Washington.</p> <p>7 And so one thing we do know if this case had 8 not left Washington and if that's where it was in 1993, 9 that Judge Dimmick's view would have been that the very 10 maintenance of the cell line that is described by 11 CellPro is, in fact, an infringing use.</p> <p>12 And so, had we stayed in Washington, I'm 13 sure that Judge Dimmick would have been quite prepared 14 to enjoin the shipment of those cells out of the 15 Washington.</p> <p>16 What is also different about this is that 17 the notion that's presented here is that these are just 18 a bunch of different vials, and that the particular vial 19 that they sent to Canada itself wasn't thawed and tested.</p> <p>20 But a hybridoma is a hybridoma. And that's 21 how a hybridoma is stored. It's stored in a bunch of 22 vials. And so you cannot simply say that every time you 23 pull one off, that you are - that that had nothing to 24 do with the 12.8 hybridoma.</p> <p>25 When you do quality-control testing of the</p>
<p>1 I do want to emphasize that, as Mr. Reilly 2 said, CellPro is a licensee from the Fred Hutchinson. 3 Nobody is talking about destroying the Fred Hutchinson's 4 12.8 hybridoma. These are simply cells that were cloned 5 off of the hybridoma at Fred Hutchinson.</p> <p>6 And our point is simply that CellPro should 7 not be permitted to continue to be in possession of 8 hybridoma cells, because it is just very easy to ship 9 them out of the country.</p> <p>10 So -- but we are not talking about killing 11 some living thing that can never be reproduced, because 12 that's exactly the point of all of the cells in the 13 freezer at Fred Hutchinson. You can simply clone more 14 off of them.</p> <p>15 I think also that what Mr. Riley is missing 16 in his discussion of widgets is that these aren't 17 widgets, and what you do with a hybridoma is you store 18 it and you test it from time to time so as to be able 19 to replenish your stock.</p> <p>20 And so that is the use. Putting hybridoma 21 into service is basically putting it into the freezer 22 and pulling cells out from time to time and doing 23 quality-control testing. So it's a very different 24 situation from widgets.</p> <p>25 And there's an interesting case that is</p>	<p>Page 39</p> <p>1 hybridoma, you're testing cells in a particular vial, 2 because the results of that test tell you something 3 about all of the cells. And so you can't just say 4 there are billions of cells, and so we only tested 5 these cells and we sent these cells. I mean, the 6 patent covers a hybridoma, and that's what a hybridoma 7 is. It's a whole lot of cells that have been cloned 8 that are all identical that are sitting in the freezer 9 in vials. So...</p> <p>10 MR. REILLY: Your Honor, the patent -- what 11 right is secured by a patent is what we need to focus 12 on. The patent doesn't really cover a hybridoma. The 13 patent covers the right to exclude others from making, 14 using and selling the hybridoma in the United States 15 during the term of the patent. That is exactly what 16 the patent covers, or is what it has been ruled to cover 17 by the Court.</p> <p>18 And, again, the fact that this hybridoma was 19 made before the patent issued and that the particular 20 six vials that were shipped to Canada just remained in 21 the frozen state since before the patent issued until 22 1993, when they were shipped up to Canada, they simply 23 were not used in the United States.</p> <p>24 As for your Honor's question about what 25 CellPro's motive is in shipping them to Canada, I would</p>

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1 first suggest to your Honor that that is irrelevant.  
 2 The only thing relevant is that Canada is not the  
 3 United States and 271(a) says that you've got to be in  
 4 the United States to infringe.

5 Beyond that, your Honor, there is --

6 THE COURT: It sounds like a good business  
 7 opportunity, if somebody could rent a hospital ship and  
 8 become some kind of a freezer bank, stay off the coast.  
 9 We hold it while you litigate?

10 MR. WARE: We hold, you litigate.

11 MR. REILLY: They don't have to hold it.

12 They can use it to their heart's content in any country  
 13 but the United States is my point.

14 THE COURT: A lot of Caribbean countries.

15 It's too hot down there. That's why you picked Canada.

16 MR. REILLY: There is some evidence that we  
 17 recently submitted on CellPro's intent.

18 On the question of -- of intent, we did  
 19 submit a declaration of Dr. Tarnowski (phonetic) with  
 20 CellPro, who reports that the hybridoma, after it got  
 21 to Canada, was thawed out and was used to make  
 22 biotinylated 12.8 antibody, which was not sold into the  
 23 U.S., I believe, but it was sold in Europe.

24 So the biotinylated 12.8 was made from the  
 25 hybridoma in Canada for sale in Europe which, again,

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1 this case. They have had a jury award them damages  
 2 based on their sales in Europe.

3 The section of the patent statute that deals  
 4 with injunctions speaks of the injunction as being a  
 5 remedy to prevent infringement.

6 Selling a stem cell antibody, making a stem  
 7 cell antibody product in Europe, where the plaintiffs have  
 8 no patent coverage and concede that they can't now get  
 9 any, is not an infringement of the U.S. patent law.

10 And if the court were to enter an injunction  
 11 granting that relief, the Court would really be giving  
 12 them a remedy that they have already had a damages remedy  
 13 for. The whole idea of a reasonable royalty damage claim  
 14 is to compensate the plaintiffs for past sales.

15 We are now talking really about future  
 16 conduct. And I think that the -- the injunction can't  
 17 really enjoin something that's not an act of infringement.

18 And to take an antibody that is wholly  
 19 developed in Europe, or to taken 12.8 antibody that has  
 20 never been in the United States during the term of this  
 21 patent, simply would not be an infringement of the U.S.  
 22 patent laws.

23 The other point on that, your Honor -- and  
 24 we've briefed this -- is the whole question of  
 25 international comity and the extraterritorial effects

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1 is lawful, given the territorial scope of the United  
 2 States patent.

3 The next point that Mr. Ware --

4 THE COURT: You could call that ship

5 Patent Pending.

6 MR. REILLY: You could.

7 THE COURT: Go ahead. I'm sorry.

8 MR. REILLY: The next point that Mr. Ware  
 9 raised, your Honor, was about the two-year prohibitory  
 10 injunction in Europe.

11 As we read that proposal, it would forbid  
 12 CellPro from making any stem cell antibody product in  
 13 Europe, even if the antibody was 12.8 that had never  
 14 even been in the United States during the term of the  
 15 patent, or even if it had been some other antibody.  
 16 And the idea is a head-start injunction.

17 I think it's -- let me get to my notes for  
 18 a moment.

19 (Pause.)

20 MR. REILLY: I think it's telling, your  
 21 Honor, that there are no patent cases that are cited in  
 22 support of this notion that you can have a head-start  
 23 injunction as a remedy for past patent infringement.

24 The remedy for past patent infringement is  
 25 the remedy that the plaintiffs have already had in

1 of patent laws, we have a declaration we filed from Mr.  
 2 Colin Overbury, who is a high official of the European  
 3 Commission, that talks about the effect that  
 4 extraterritorial enforcement of U.S. patent laws would  
 5 have on the important antitrust and competition policies  
 6 of the European union. And he opines that this is  
 7 something that would implicate the comity issues and it  
 8 could provoke international retaliation.

9 The other thing I would say, to go on about  
 10 these trade secret cases, is that they really, really  
 11 are distinguishable, when you consider the difference  
 12 between what a trade secret is and what a patent is.

13 Trade secrets are creatures of state law.  
 14 The cases are cases the plaintiff cites, where the Court  
 15 is sitting in diversity and applying state law. Trade  
 16 secrets aren't necessarily territorial in scope. You  
 17 can come in and steal somebody's trade secret and you're  
 18 still a thief. If you come into the United States and  
 19 see somebody's patented device in operation, you are  
 20 free to take it with you and use it anywhere where he  
 21 does not have patent coverage.

22 I would say, too, that the -- there's an  
 23 international network of cooperating patent laws that  
 24 really finds no counterpart in trade secret law.  
 25 Trade secret law is basically a state common-law thing

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1 that recently has been -- relatively recently has been  
2 codified in some states.

3 Whereas you look in the patent laws, and the  
4 U.S. patent laws are carefully tailored to intermesh  
5 with international patent laws. There are -- wherein  
6 all countries respect the territoriality of each  
7 other's patent laws and expect that they will not  
8 apply extraterritorially.

9 And to render -- issue an injunction in a  
10 patent case that has extraterritorial effects that  
11 would say to CellPro, Even though your activities in  
12 Europe do not infringe any U.S. patent and can't,  
13 because they're beyond the territorial scope of that  
14 patent, still we are enjoining you for patent law  
15 reasons.

16 That would be an extraterritorial  
17 enforcement in a situation where you've got a rather  
18 complex international scheme of rights, all countries --  
19 each country understands that its own patent laws are  
20 territorial. And the way the European union would be  
21 if these plaintiffs wanted patent protection in Europe  
22 to prevent their business competitors from selling a  
23 stem cell antibody product in Europe, they should have  
24 gotten patent production here.

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2 MR. REILLY (Continuing): So there are  
3 extremely large and significant differences between  
4 the nature and scope of the right that patent confers  
5 and the right that trade secret protection confers.

6 The right that trade secret protection  
7 confers is simply a right to prevent people from, you  
8 know, invading your secret and igniting it. The right  
9 that patents confers is a right to exclude others for  
10 a limited term in a limited place that in this case does  
11 not include Europe.

12 So, for all these reasons, we think that  
13 the trade secret cases are totally inapt. There's a  
14 good reason why they cite trade secret cases and not  
15 patent cases. And there are serious issues of  
16 international comity that would be implicated if that  
17 kind of an injunction were issued.

18 MR. WARE: I think I have about three or  
19 four very quick comments.

20 First, on the trade secret cases, it's  
21 actually interesting. Trade secret law is a creature  
22 of state -- of the states, not federal, and those trade  
23 secrets are, in many cases, not even recognized in many  
24 foreign countries, and yet certainly courts in the  
25 United States feel perfectly able to enter orders like

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2 MR. REILLY (Continuing): They did not fill  
3 the requirement to get patent protection in Europe, so  
4 they have not got it. So free competition is what  
5 should obtain.

6 Trade secrets are worldwide. And trade secret  
7 is a potentially -- I should not say infinite, but  
8 indefinite duration. As long as it remains a secret, it  
9 is entitled to trade secret protection.

10 By the same token, if you reverse-engineer a  
11 trade secret -- if you make something that tastes just  
12 like Coca-Cola without cracking the safe and getting the  
13 Coca-Cola formula, then you are perfectly legal to do  
14 that.

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1 this and would certainly similarly feel comfortable  
2 entering an order against a United States company that  
3 steals trade secrets in the United States and ships  
4 products out, or ships confidential work papers or  
5 scientific technical papers out.

6 They could be ordered to bring them back  
7 even if they had shipped them to -- I was going to say  
8 China, which maybe does not recognize them, or even if  
9 they've got them on that offshore tender somewhere.

10 THE COURT: Even if they take them to Spain  
11 and Germany and they used to work for Ford Motor  
12 Company.

13 MR. WARE: These things do happen from time  
14 to time.

15 And the United States courts do exercise  
16 their authority to provide remedies that are meaningful  
17 remedies for past violations.

18 And the Federal Circuit has made clear on  
19 a number of occasions that it is perfectly within the  
20 authority of a District Court to enter injunctions that  
21 not only prevent future infringement, but that remedy  
22 past infringement, that will have an impact in the  
23 future if not remedied.

24 And that's what's going on here. There have  
25 been injunctions entered even in medical cases where an

<p>1 infringer has been ordered to destroy clinical data that 2 was generated through infringement. That's the Pfizer 3 case. And the data itself is not infringing, but it's 4 a remedy that was granted.</p> <p>5 And we are not asking for that particular 6 remedy, but we are asking for remedy for conduct in the 7 United States that unfairly impacts the future 8 development of Baxter's business in Europe as a result 9 of the head start.</p> <p>10 So I guess I'd move on now to the stay of 11 the injunction.</p> <p>12 MR. REILLY: If I may just respond to that 13 very briefly, your Honor...</p> <p>14 THE COURT: Yes.</p> <p>15 MR. REILLY: Again, for past infringement, 16 they've already had their remedy. They've now gotten 17 the verdict for damages on a reasonable royalty theory.</p> <p>18 The other point to keep in mind about this 19 head start injunction in Europe is that the logic of 20 such an injunction I think has not really been 21 supported in the proof. Plaintiffs assert in their 22 briefs that, but for infringement in the United 23 States, we would never have gotten going in Europe. 24 It's nowhere been proved on this record 25 that that is true. And, in fact, Dr. Tarnowski's</p>	<p>Page 50</p> <p>1 they are doing the manufacturing in the United States, 2 in Bothell, Washington, and that what we're actually 3 talking about is an injunction that will have — will, 4 in the end, amount only to enjoining them from 5 exporting goods from the United States.</p> <p>6 There's no evidence that they have any 7 other plans anyway. So in terms of the impact of this 8 injunction, it may be only United States activities 9 anyway.</p> <p>10 MR. REILLY: Well, your Honor, I would 11 invite Mr. Ware to withdraw that part of his proposal 12 that would call for an injunction in Europe. That's why 13 we have this issue.</p> <p>14 MR. WARE: But if you are manufacturing in 15 the United States, you can't even raise this point.</p> <p>16 MR. REILLY: All right. I think my problem, 17 your Honor, is that the injunction, the proposed 18 injunction, as written, would forbid CellPro for two 19 years from making any stem cell antibody product in 20 Europe, regardless of where they got the antibody. And 21 if they didn't get it in the United States during the 22 term of the patent, it simply does not infringe.</p> <p>23 And what CellPro may do later, I mean, 24 certainly, it is a business option for any company that 25 is blocked under U.S. patent law to manufacture where</p>
<p>1 recently-filed declaration demonstrates that CellPro 2 could have, and did, for a while, manufacture the 3 biotinylated antibody in Europe.</p> <p>4 And the reason why he stopped was that we 5 won the trial in 1995. —</p> <p>6 And so the logic kind of breaks down that, 7 but for this infringement, we never would have gotten a 8 head start in Europe. We could have manufactured 9 outside the United States, and that's perfectly proper 10 and encouraged by the laws of other countries.</p> <p>11 So I think the basic premise is — really 12 isn't there, whereas, again, in a trade secret case, it 13 is there, because, by definition, when you steal a 14 trade secret and exploit the trade secret, you're 15 getting some kind of a head start from the trade secret. 16 that you couldn't have gotten without the trade secret. 17 CellPro could have gotten the same head start by 18 manufacturing outside the United States, which they 19 would have if they had thought there was any reason to 20 do it. And, indeed, they did for a while.</p> <p>21 MR. WARE: Yes. The interesting thing about 22 this argument is that CellPro has never actually told 23 us in opposing this injunction what they actually plan to 24 do, as far as foreign manufacturing and sales.</p> <p>25 I believe what's going on is actually that</p>	<p>Page 51</p> <p>1 its business competitor has not seen fit to get himself 2 patent protection, such as in Europe.</p> <p>3 I can't represent to the court that CellPro 4 right now, today, is starting manufacturing operations 5 in Europe. They may be. They may not be. I just 6 don't know the answer to that question. But they 7 certainly ought to be welcome to do it. And the 8 plaintiffs are proposing a form of injunction that 9 would prohibit them to do it, even though it wouldn't 10 be an infringing act if they did do it. That's my 11 problem.</p> <p>12 THE COURT: All right.</p> <p>13 MR. WARE: If we can move on to the stay...</p> <p>14 THE COURT: All right.</p> <p>15 MR. WARE: I think that, analytically, it 16 helps to sort of subdivide the stay into several areas. 17 One is United States versus the rest of the world and 18 what we have proposed is different in the United States 19 from in the rest of the world.</p> <p>20 And the second is subdivision between 21 CellPro's commercial sales of its device for the rather 22 limited FDA approval, approved indication that it has 23 versus the clinical trials.</p> <p>24 And then within the clinical trials, 25 there's really a subdivision as between clinical trials</p>

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1 that are ongoing and have been approved by the FDA, and  
 2 the applicable IRB, and clinical trials that simply  
 3 might be proposed at some point in the future.

4 I think, as to commercial sales in the United  
 5 States, there's not a whole lot that needs to be said,  
 6 except to come back in a few minutes to the issue of the  
 7 incremental profit payment on those sales. But I don't  
 8 think there's any serious objection to the scope of the  
 9 stay and the terms of the stay with respect to  
 10 commercial sales.

11 The thrust of CellPro's objections relates  
 12 to clinical trials. And as we have made clear in the  
 13 papers that we have filed, it was never the plaintiffs'  
 14 intention to preclude CellPro from continuing to supply  
 15 those clinicians who are engaged in FDA-approved  
 16 clinical trials.

17 We do believe, however, that there is no  
 18 reason why CellPro should be able to conduct clinical  
 19 trials indefinitely, that is to start new clinical  
 20 trials, because in that realm, there are two products  
 21 available to a clinician, neither of which currently  
 22 has FDA approval with respect to the particular uses  
 23 in the clinical trials.

24 If CellPro had FDA approval, they couldn't  
 25 be doing clinical trials. And so CellPro's device is

1 more disruptive to permit an infringer providing  
 2 infringing products.  
 3 The arguments presented by CellPro in  
 4 its filing last week are principally -- principally  
 5 amount to disparagement of Baxter's product.  
 6 And we have filed a motion to strike those  
 7 declarations. We do not think that it is proper for  
 8 the Court to consider ex-parte declarations filed  
 9 post-trial. Those deponents have never -- declarants  
 10 have never been deposed or cross-examined. They were  
 11 not identified in the pretrial order. The facts on  
 12 which they rely were not identified in the pretrial  
 13 order. And as the Shytle (phonetic) case indicates,  
 14 in a case involving Lyon & Lyon itself, this is not a  
 15 proper way to decide the scope of an injunction.

16 We have, nevertheless, submitted on behalf  
 17 of the plaintiffs some declarations on very short  
 18 notice, which I think makes clear that the Baxter device  
 19 is a -- is an entirely acceptable device that clinicians,  
 20 in fact, use. It's installed in more than 40 cities  
 21 around the United States and Canada, at some of the  
 22 most prestigious institutions, hospitals and other  
 23 institutions. Clinicians are very satisfied with it.

24 It works well.

25 In fact, it has comparisons -- in

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1 every bit as much experimental in that particular  
 2 indication as is Baxter's.

3 And the concern here is that these are --  
 4 this is a situation where CellPro, if permitted to  
 5 continue forever doing these clinical trials with the  
 6 SC device, could make it extremely difficult for  
 7 Baxter to ever establish a market for a commercial  
 8 market, because I'm sure clinicians are quite content  
 9 to continue to receive supplies for free or at a very  
 10 reduced cost. And these are situations where there's  
 11 absolutely no reason why the clinician cannot specify  
 12 the Baxter Isolex device in a future trial.

13 So we are not proposing that they must  
 14 substitute the device in a current trial. But -- so  
 15 we think it's appropriate to draw that distinction.  
 16 And I think that, really, in terms of the public  
 17 interest, if anything, it is more disruptive, if  
 18 you're looking down the road to the future to a trial  
 19 that hasn't even been proposed to the FDA yet, that it  
 20 is really even more disruptive for the clinicians  
 21 themselves and the hospitals themselves to embark upon  
 22 clinical trials using a product that ultimately will  
 23 be enjoined from use.

24 And so, therefore, just as Judge Farnan  
 25 indicated in the Critikon case, it can be actually

1 comparisons with CellPro's device, it has been shown to  
 2 work, to provide better results and to be every bit as  
 3 easy to use, if not more so.

4 So the Court certainly should not deal  
 5 with this issue of a stay based upon the assumptions that  
 6 the plaintiffs or a licensed party under the patents has  
 7 nothing to offer that will address the medical need.

8 So what we have tried to do is we have tried  
 9 to craft a stay that will assure that there is no patient  
 10 who will be deprived of access to the inventions that  
 11 Dr. Civin made at Johns Hopkins University. But this  
 12 needs to be a transition period. It cannot go on  
 13 forever.

14 I anticipate from CellPro's papers that  
 15 the argument is now being asserted that as to the  
 16 clinical trials, that somehow the injunction can't cover  
 17 them because of Section 271(e). And I remind the Court  
 18 that, at the last hearing we had on March 13th, counsel  
 19 for plaintiff stood up and acknowledged that there was  
 20 no Section 271(e) in the -- defense in the case. It was  
 21 not raised by CellPro in the answer. It was not raised  
 22 in the pretrial order.

23 CellPro would have had to prove that the  
 24 particular supplies of products to institutions engaged  
 25 in clinical trials were actually exempt under Section

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<p>1 271(e). That's a burden that they did not undertake.      2 And, therefore, they cannot now complain that an      3 injunction will encompass sales or supply of products      4 that somehow they might have proven to be exempt under      5 Section 271(e).</p> <p>6 In fact, as we indicated in our papers, we do      7 not think that they could have made that -- met that      8 burden of proof in any event, because that exemption is      9 a very narrow one that relates to uses that are solely --      10 solely for developing FDA information, and CellPro      11 certainly could not say when it makes the 12.8 antibody      12 that it is doing so solely for purposes of FDA reporting      13 requirements, because it has a commercial device. The      14 commercial device is on sale in the United States and      15 in Europe.</p> <p>16 But, in any event, that issue simply is not      17 before the Court and it is a red herring.</p> <p>18 I think that it might make sense to stop now.      19 I have some comments on the incremental profit and I have      20 a few more comments -- although I think we pretty much      21 covered the European sales issues. But I think I will      22 stop right now.</p> <p>23 THE COURT: Okay.</p> <p>24 MR. REILLY: Your Honor, if I may respond to      25 that, I think what counsel was alluding to for part of</p>	<p>1 sale or selling the SEPRATE SC except      2 for use in clinical trials meeting the      3 requirements of the exception stated      4 in," and then they cite 271(e)(1) and      5 271(e)(3).</p> <p>6 So it certainly was in the issues that      7 were stated.</p> <p>8 As to whether the parties were expected to      9 put in all their proof relevant to the injunction at      10 the trial, I would remind the Court of a couple of      11 things. The plaintiff successfully moved for an order      12 in limine, which forbade CellPro to do anything that      13 would intimate to the jury that there even might be an      14 injunction in this case.</p> <p>15 So we couldn't very well put in all our      16 proof relevant to the injunction issue at the trial in      17 light of the motion in limine.</p> <p>18 Furthermore, the injunction, proposed form of      19 injunction, was something we never saw until after the      20 trial, and all kinds of issues that it raises, such as      21 what would be the public health impacts, the impacts on      22 CellPro to have this \$2,000 per unit price, to have a      23 prospective two-year injunction in Europe, and a host      24 of other issues that pop out at you when you read the      25 proposed injunction, but not before, couldn't possibly</p>
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<p>1 the time was the paper we recently received wherein      2 the plaintiffs have moved to strike our declarations      3 that deal with issues, including the 271(e)(1) issue.      4 As to the late service point, Mr. Ware didn't      5 get into it, and perhaps neither should I, but I      6 understand that the Fed Ex people failed to come and pick      7 up the declarations and get them to Boston on the night      8 when they were left for Fed Ex to get them.</p> <p>9 Local counsel received them timely. Counsel      10 in Boston received them a day late. And to the extent      11 that there's any innuendo in the brief that this was      12 deliberate, I understand that Mr. Powers, our local      13 counsel, is prepared to explain how this all happened, if      14 the Court wants to hear about it.</p> <p>15 As for the point about 271(e)(1) not being      16 in the pretrial order, it was in the pretrial order, and      17 the plaintiffs themselves put it there.</p> <p>18 If one goes to plaintiffs' statement of      19 issue of law No. 9, which is found under Pages 9 -- at      20 Pages 9 and 10 under Tab 3 of the pretrial order, they      21 frame the injunction issue thus:</p> <p>22 Quote, "Whether plaintiffs are      23 entitled to an injunction prohibiting      24 CellPro" -- "CellPro from importing,      25 exporting, making, using, offering for</p>	<p>1 have been fairly expected to have been addressed at      2 trial.</p> <p>3 And I think the last time the Court really      4 went on record as to what it expected to be done about      5 the injunction and how it saw this issue being handled      6 was at a hearing. Before the last trial -- I have a      7 February 21st, 1995 transcript and at Page 29 of that,      8 Lines 2 through 14, the Court said, and again I'm      9 quoting:</p> <p>10 "Here's what I think I will do.      11 I am generally familiar with the case      12 law that talks about situations where      13 a Court may not grant an injunction      14 because of the public interest in having      15 health care products on the market. I      16 think what I will do is simply defer the      17 discovery on that. If we get a jury      18 verdict, and the plaintiffs pop up and      19 say, Judge, enter an injunction today, we      20 can then have a discussion about what      21 further information CellPro may want in      22 order to oppose the entry of an injunction      23 at that point. We may know at that point      24 where the FDA is on these products."</p> <p>25 And your Honor goes on with other comments</p>

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1 along those lines.  
 2 I think it's pretty clear from that -- and  
 3 we certainly understood -- that the court contemplated  
 4 some separate determination preceded by discovery of  
 5 some kind on the exact form and scope that any  
 6 injunction might take. That's a fair way to handle it.  
 7 That's how we thought it would happen. That is how we  
 8 expected it to happen.

9 And, indeed, it is really the only way that  
 10 it can happen, given the order in limine that prevented  
 11 any kind of meaningful ventilation of the injunction  
 12 issues during the jury trial.

13 And when we weren't yet on notice of the  
 14 proposed injunction, the details of the proposed  
 15 injunction they would seek. And a lot of very  
 16 important objections go to those details.

17 So that answers their motion to strike the  
 18 declarations. I think the declarations are fairly in  
 19 the case.

20 Now, if I may move on to the substance of  
 21 it, counsel calls the 271(e)(1) issue a red herring. It  
 22 is not, for several reasons. The most fundamental of  
 23 them is the 271(e)(1), when you read it together with  
 24 271(e)(3), imposes an explicit limitation on judicial  
 25 power. (e)(3) says no injunction, or other relief,

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1 enrich the stem cells with the use of other antibody to  
 2 enrich or deplete for other kinds of cells. And those  
 3 are being FDA tested right now.  
 4 And under 271(e)(1), CellPro has a perfect  
 5 right prospectively to do that.  
 6 To counsel's point that we somehow waived the  
 7 right to rely on 271(e) by not asserting it as a damage  
 8 defense, I think that view misapprehends the difference  
 9 between prospective remedies and retrospective remedies.

10 Damages is a retrospective remedy. That's  
 11 for what you've already done. And from the fact that  
 12 CellPro chose not to argue that a portion of its past  
 13 sales were FDA exempt should in no way foreclose CellPro  
 14 from arguing that if, in the future, it wants to do  
 15 things that are FDA exempt, it can.

16 The prospective aspect of this has nothing  
 17 to do with the retrospective aspect of it. On the face  
 18 of their own statement of issues of law, the plaintiffs  
 19 acknowledge that 271(e) is the immovable object here.  
 20 An injunction that does not make allowance for 271(e)  
 21 exempt uses is an injunction that is on its face  
 22 overbroad and I think unlawful.

23 I just don't think that the Court could sign  
 24 it in the form in which plaintiffs propose it without  
 25 running afoul of two 71.

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1 may be granted which would prohibit the making, using,  
 2 selling or offering to sell in the United States a  
 3 patented invention solely for reasons related to FDA  
 4 approval.

5 It's kind of a rare thing, I think, in  
 6 federal statutes where you have one section saying the  
 7 Court can issue injunctions and then you have a separate  
 8 and more specific section saying the injunction may not  
 9 forbid this.

10 So it's -- patent rights are creatures of  
 11 statute and the remedies that can be granted are  
 12 limited by statute. And in this case Congress has  
 13 determined that it simply is not an act of infringement  
 14 to use someone's patented technology for purposes of  
 15 getting your FDA approvals ready.

16 For that reason, it would, I think, be --  
 17 it would be violative of 271(e)(3) if the Court were to  
 18 enter the injunction in the form that plaintiffs  
 19 request, because as long as something is a bona fide  
 20 FDA study that is aimed at either what is called a  
 21 label expansion, to get an approval to sell the device  
 22 and advertise it for another use, another indication, or  
 23 a new device approval -- and CellPro, as we point out  
 24 in our declarations, has some second-generation devices  
 25 that would combine the use of the 12.8 antibody to

1 Now, just what is a 271(e)(1) exempt use is  
 2 something that can be debated later. But an injunction  
 3 that says you can't make any uses that -- that says you  
 4 may make uses that are 271(e)(1) exempt is certainly,  
 5 I think, what it would have to say. The injunction  
 6 would have to carve out that exception if an injunction  
 7 were entered at all.

8 And the fact that CellPro has a commercial  
 9 product I don't think is sufficient as a matter of law  
 10 to support a conclusion that there can be no conceivable  
 11 use of that product that would be exempt.

12 We have in approximately 20 of our  
 13 clinicians' declarations and also in the declaration of  
 14 Dr. Cindy Jacobs, who's CellPro's Director of Clinical  
 15 Research, we talk about a number of studies that are  
 16 going on, 50 or 60, I think, in the United States alone  
 17 at this point, and in some Europe that are under IDE's  
 18 and are for the purpose of gathering data to either do  
 19 a label expansion or to get a new device approval.

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2       MR. REILLY (Continuing): Those are not  
3 commercial sales. They can be made at a commercial  
4 price. There is an FDA regulation and it is Mr. David  
5 Wied's declaration that gets into this. He is the  
6 person who is the former Deputy Counsel, I think, of the  
7 FDA. He explains that when you supply medical devices  
8 in support of a clinical trial, you can sell them at  
9 retail. You can at most charge only a cost recovery  
10 price.

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1 to drawing the line at present - presently under way  
2 trials. Under the law, it simply is not an act of  
3 infringement, and it cannot be enjoined if a company uses  
4 the patented technology to seek FDA approvals.

5       This was debated in Congress and the  
6 plaintiffs' side lost on that question. It's simply  
7 exempt and you can't read it out of the law. It is a  
8 limitation on judicial power.

9       One more point that I wanted to make on that.  
10 Just on the point of why the injunction will be overbroad  
11 on its face if it failed to make allowance for 271(e)(1)  
12 exempt activities, there are a number of things that  
13 CellPro would have to do to support its FDA trials,  
14 whether it was making a commercial product in the  
15 United States or not.

16       And, as I understand the injunction, it would  
17 prevent CellPro, at least after Baxter got an FDA or some  
18 licensee got an FDA approval, from even using the CellPro  
19 device for its one approved application, which is bone  
20 marrow transplantation for breast cancer.

21       If that use were enjoined, then just about  
22 everything else that CellPro would be doing would be in  
23 support of some kind of an IDE.

24       As for the notion that CellPro could somehow  
25 go hog wild and just do some unlimited number of clinical

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2       MR. REILLY (Continuing): And as Dr.  
3 Jacobs' declaration explains, some of the doctors expect  
4 reduced-priced goods or they won't participate in trials  
5 and some of the patients can't afford it unless the  
6 devices are supplied cheaper or free.

7       Now, I think Mr. Ware has basically conceded  
8 that point. I see that his revised form of injunction,  
9 at least for present clinical trials, that is once  
10 already under way, would exempt from this \$2,000 per  
11 unit sold royalty rate any CellPro disposables that  
12 are supplied in connection with these FDA trials.

13       I think that is correct, and that's how it  
14 has to be. I think anything else would run afoul of  
15 271(e)(1).<sup>1</sup>

16       So the main point, your Honor, is that a  
17 large amount of the uses of the CellPro device that are  
18 going on presently are in support of - either CellPro-  
19 sponsored or investigator-sponsored investigational  
20 device exempt uses that have been cleared with the FDA,  
21 and these are uses being made for the purpose of  
22 either getting a label expansion or getting a new  
23 device approval, and it's exactly what 271(e)(1)  
24 permits.

25       There's absolutely no basis in law or in logic

1 trials for some bad-faith reason, I think the best answer  
2 to that is that's a problem for the FDA; it's not a  
3 problem for this Court.

4       And the FDA has ways to deal with that.  
5 Again, I would refer the Court to Mr. Wied's declaration,  
6 which I think makes the point, and Dr. Jacobs' does also:  
7 That the FDA does not let you use clinical trials just to  
8 get out there and do commercial distribution. They won't  
9 let you charge a commercial price. They won't let you  
10 test market. They won't let you advertise the product  
11 for that use. And they want to know that it's real  
12 science that you are doing, and they want to see your  
13 protocol.

14       And once you have your IDE, you'd better  
15 not depart from the protocol. You'd better treat only  
16 the patients who say you'll treat and only the way you'll  
17 say you'll treat them, and you'd better also comply with  
18 all the reporting and data-gathering requirements,  
19 because the purpose of an IDE is not to be some kind of  
20 a blind for commercial sales.

21       And, in fact, the FDA can, and does, revoke  
22 IDE permissions if it sees someone is using them as a  
23 blind for commercialization. I think that's something  
24 the FDA can police and this Court does not have to.

25       MR. WARE: It seems like this is a good

1 moment to jump in.

2 MR. REILLY: I think it is.

3 THE COURT: All right.

4 MR. WARE: Okay. Well, several comments.

5 First, as a sort of procedural posture, I  
6 think at the time the statement in the pretrial order  
7 that counsel referred to was done, I think that  
8 plaintiffs thought that perhaps it was CellPro's  
9 intention to raise this. But they did not. They made  
10 it clear they were not.

11 They even provided, with respect to damages,  
12 they provided a statement of all of the revenue received  
13 from SC - the SC device, which quite explicitly included  
14 the cost of recovery sales as well, and did not assert a  
15 271(e) defense.

16 Mr. Reilly suggested that, while there's a  
17 big difference between damages and a future injunction,  
18 but what they actually did was they did not assert the  
19 defense as to liability either. And that statement is  
20 actually made in a brief that was filed in this court  
21 on March 13th, 1997. And we cite it in our brief.

22 They stated, We have not asserted a 271(e)  
23 defense to liability or damages.

24 If you are going to take the position that  
25 particular sales and uses of your product are

1 they should all be subject to the injunction.

2 It is also not enough to simply recite the  
3 phrase clinical trial and say that they're exempt. There  
4 is a serious factual issue about the 271(e) exemption  
5 because of the use of the phrase "solely" in the statute,  
6 which would be read out of it entirely under Mr. Reilly's  
7 argument.

8 So that there are real issues that would have  
9 to actually have been presented and tried to -- for  
10 CellPro to establish that certain types of sales were  
11 noninfringing and protected under Section 271(e).

12 The suggestion that certain sales or uses of  
13 the device must be for 271(e) purposes, because they're  
14 being used in clinical trials, overlooks the fact that  
15 that isn't the point -- or that's certainly not the first  
16 point, when CellPro has infringed. CellPro has  
17 infringed the '204 patent when it has made the 12.8  
18 antibody. And when it makes the 12.8 antibody, it  
19 certainly cannot say that its infringement is solely  
20 for seeking FDA approval.

21 But that defense is not in the case and it  
22 certainly was never contemplated in the pretrial order  
23 and it certainly was never discussed with this Court  
24 before the trial in March that we were then going to have  
25 another trial after the completion of that trial at which

1 noninfringing by reason of 271(e), you would be asserting  
2 a defense to liability. That defense was not asserted,  
3 so that -- so that all of the types of trials that are  
4 going on now were treated by CellPro as no different from  
5 the commercial sales, and there simply is no basis, legal  
6 or factual, in the circumstances to then take the  
7 position that, well, all those sales are noninfringing  
8 under 271(e) and, therefore, the Court can't enter an  
9 injunction.

10 The approach that Mr. Reilly is suggesting is  
11 one that the Federal Circuit has said is improper. In  
12 the Eli Lilly V. Medtronic case, or one of the Eli Lilly  
13 versus Medtronic cases, which we cite in our brief, the  
14 Court said that you don't just -- you don't enter an  
15 injunction that says that it's subject to whatever  
16 271(e) exemption there might be. That is an issue --  
17 that's a liability issue. And so that the defendant  
18 has to actually prove that particular sales are sales  
19 that are noninfringing under 271(e).

20 So if that does not happen, they get  
21 enjoined. Those sales have been found to be infringing  
22 sales.

23 There was no exception in the Court's  
24 determination that CellPro was infringing for any  
25 particular types of sales. They are all infringing and

1 there would then be testimony and evidence presented in  
2 order to establish a 271(e) defense that would go to the  
3 scope of the injunction. That was never discussed, never  
4 contemplated. And CellPro made its choice when it decided  
5 not to raise a 271(e) defense.

6 I think it recognized that it would have a  
7 very difficult time establishing a 271(e) defense, and it  
8 did not choose to do that.

9 THE COURT: Why? Why would it have a  
10 difficult time?

11 MR. WARE: Because of the "solely" language  
12 in the statute. It is -- there is only an exemption  
13 where the infringement that is done is infringement  
14 solely for purposes of meeting FDA requirements. And  
15 that simply is not the case here, because they have --  
16 they make the 12.8 antibody for all kinds of purposes  
17 and uses which have nothing to do with FDA approval;  
18 i.e., selling the product commercially in the United  
19 States and in Europe.

20 So -- but, in any event, it's a question  
21 of fact. It's one that has to be determined as a  
22 liability question. And if a party does not raise it,  
23 they are not entitled to come in afterwards and raise  
24 it. And they are not entitled, then, to -- when an  
25 injunction is entered, to then say, Well, now, every

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1 time that we're accused of violating the injunction, we  
 2 have to come in and have a factual determination of  
 3 whether or not that particular activity was infringing  
 4 because of 271(e).

5 That's exactly what the Federal Circuit said  
 6 they did not want to have happen and that issues that go  
 7 to liability of whether a party is infringing or is  
 8 exempt from infringement under 271(e), that's supposed to  
 9 be tried as part of liability. And if a party waives  
 10 that defense, it is not in the case.

11 As far as the future trials, too, the other  
 12 thing I wanted to suggest is -- I mean, the point of --  
 13 to the extent that there -- let me back up.

14 The point of the statute was to -- to allow  
 15 a certain -- certain activities sort of in the period  
 16 before the patent expired. We're talking about a patent  
 17 that expires ten years from now. And clinical trials  
 18 that CellPro might start at this time are certainly not  
 19 ones that are designed to put it in a position to offer  
 20 a product when the patent expires.

21 And there is a serious disruption and harm  
 22 to Baxter by permitting CellPro, in effect, to just  
 23 indefinitely engage in clinical trials.

24 And so that's why we're talking about an  
 25 injunction that the -- the injunction on its face would

1 safe and effective for that use. It's still  
 2 experimental.

3 And so, as we pointed out in our papers, for  
 4 those clinical trials, the Baxter product and the  
 5 CellPro product are both in the same boat.

6 Something came across my desk yesterday that  
 7 I would like to bring to the Court's attention, because  
 8 it relates to this very argument that CellPro made, that  
 9 its own FDA approval gives it some special availability  
 10 to clinicians. And this is a letter that I was unaware  
 11 of until yesterday that was written to CellPro by the  
 12 FDA earlier this year that is highly critical of  
 13 CellPro's actions in promoting its product to doctors  
 14 for other than its approved use.

15 And it actually told CellPro that what it  
 16 was doing was misbranding the product, that it was  
 17 making misrepresentations about the product, that it  
 18 was making statements that are regarded by the FDA to  
 19 be false and misleading.

20 And I would like to submit that to the  
 21 Court (handing document to the court).

22 THE COURT: Do you want to identify the date  
 23 and author?

24 MR. WARE: Yes.

25 MR. REILLY: Your Honor, I would object to it,

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1 cover all of these activities. We're then talking about  
 2 the scope of the stay from that injunction. And we do  
 3 not think that the Court is required, or should enter  
 4 such a broad stay as to really eliminate for the next  
 5 ten years any serious effect of the permanent injunction.

6 So that's a different -- that's the  
 7 difference there.

8 One other thing I wanted to say, I was pleased  
 9 to hear actually Mr. Reilly's comment about the  
 10 limitations on the approved use of the CellPro product  
 11 and his acknowledgment that offering that product for  
 12 uses other than the limited approved use that he referred  
 13 to is improper.

14 A considerable amount of time was --  
 15 considerable amount of space in CellPro's declarations  
 16 that it filed and in its opposing brief were devoted to  
 17 the argument that, because CellPro had an approved  
 18 product, that somehow that made it much more appropriate  
 19 than the Baxter product, even for uses that were not the  
 20 approved uses.

21 And that argument runs directly into the  
 22 FDA's very strict limitation on what an approved use is.  
 23 And anything other than what the FDA has authorized as  
 24 the approved use is an experimental use as to which no  
 25 decision has been made by the FDA as to whether it is

1 first for lack of notice, and, secondly, as irrelevant to  
 2 any question that's before the Court.

3 (Mr. Ware handed document to Mr. Reilly.)

4 MR. WARE: Just for the record, this is a  
 5 letter -- I can't read the date. It appears to be  
 6 January something, 1987. And just so there's no  
 7 mystery about where --

8 THE COURT: '97?

9 MR. WARE: 1997. January 1997 from the FDA  
 10 to Monica Krieger of CellPro. She is the chief  
 11 regulatory person. This letter was sent to Baxter's  
 12 Law Department anonymously from someone at CellPro who  
 13 evidently believed that the conduct of CellPro in this  
 14 regard was, indeed, inappropriate. And I just learned  
 15 of this letter yesterday.

16 But I think that that should be in the record  
 17 because I think that the record presents a very  
 18 misleading argument with respect to the -- the  
 19 availability of the CellPro device to be used for so-  
 20 called off-label purposes. That appears in several of  
 21 the declarations, including Mr. Wida's declaration, I  
 22 believe.

23 And so from the FDA's perspective, that's not  
 24 the case. It's not appropriate. And so any such use  
 25 needs to be under an authorized IDE, just as does

<p>1 currently any use of the Baxter device.</p> <p>2 And so that's -- that's why, I think, that it 3 is important, as we look down the road towards future 4 clinical trials, to recognize that these are two products, 5 either one of which can be specified by a clinician for 6 a clinical trial, and that there is -- there is no public 7 health concern of the nature raised by CellPro with 8 respect to its current clinical trials when we are 9 focusing on the future.</p> <p>10 So I think what I would -- I think it would 11 make sense to turn to a few comments about the 12 incremental profit calculation.</p> <p>13 MR. REILLY: If I may just respond to some 14 of these points briefly...</p> <p>15 This letter, your Honor, as I understand it, 16 CellPro put around a Christmas card. They had on it a 17 drawing by some little child whose life had been saved 18 by the CellPro device. And there was a little 19 biographical blurb about the kid on the back of the 20 Christmas card that said what the child had been 21 successfully treated for. And it was off-label use. And 22 the FDA felt that that was inappropriate.</p> <p>23     ---</p> <p>24</p> <p>25</p>	<p>Page 78</p> <p>1</p> <p>2 MR. REILLY (Continuing): And once a device 3 is FDA-approved for one indication, it may be sold in 4 interstate commerce.</p> <p>5 Once it is sold in interstate commerce, 6 any physician within the bounds of state law and 7 professional ethics may make the judgment that it ought 8 to be used to treat a certain patient in a certain way, 9 as long as it's not advertised for that use, as long as 10 the doctor doesn't basically proceed on other than an 11 one-by-one medical judgment basis. Off-label uses are 12 permitted.</p> <p>13 And I would refer the Court to the 14 declaration of Mr. Wida, the former Deputy Counsel of 15 the FDA. Paragraph 7, specifically, talks about 16 off-label uses. And it says, off-label uses are 17 allowed. And they're quite common. The difference is 18 if you have an unapproved device that's not approved for 19 any indication, it may not move in interstate commerce 20 for the treatment of human patients at all, except as 21 part of a clinical trial.</p> <p>22 So that physicians are relatively free to -- 23 for humanitarian reasons, make an off-label use of an 24 FDA-approved device on a particular patient in 25 particular circumstances. The FDA does not disapprove</p> <p>Page 79</p> <p>1</p> <p>2 MR. REILLY (Continuing): As I understand it, 3 just because I think the record is in a very confusing 4 state about this.</p> <p>5 Off-label use is something that the FDA does 6 not control. Advertising of a medical product in 7 interstate commerce for an off-label use is something 8 that the FDA controls. The FDA does not, however, 9 regulate the practice of medicine.</p> <p>10     ---</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>Page 80</p> <p>1</p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p>1</p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>Page 81</p> <p>1 that. They would disapprove it if he advertised that 2 he was doing that.</p> <p>3 But that's where it goes. And I mean that's 4 where it stops. And so there is a significant advantage 5 to having a device that's FDA-approved from one 6 indication. And, in fact, we have among our declarations 7 Dr. Wida's -- Mr. Wida's declaration explains at great 8 length why it is that the idea that Baxter, with just a 9 patchwork quilt of IDE's and no FDA approval for any 10 indication, cannot fill the gap in patient care 11 availability.</p> <p>12 That would happen if the CellPro device were 13 frozen at the number of columns that CellPro had in use 14 as of March 12, which is what their injunction proposes. 15 That March 12 date is a scant three months after CellPro 16 got its FDA approval.</p> <p>17 I think there is something like 50 or 60 18 sites in the United States that have CellPro devices 19 right now. And there are a lot more cancer patients 20 and a lot more places than that.</p> <p>21 So this business about off-label use and 22 whether Baxter and CellPro are in the same boat, other 23 than for the indicated use, I think is an important thing 24 to dwell on for a moment, because it is just absolutely 25 infeasible that Baxter, without an FDA approval, could</p>	

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1 completely satisfy the needs of patients for treatment.  
 2 There are very, very significant constraints  
 3 on the ability of physicians to make choices in patient  
 4 treatment when they've got only an unapproved device to  
 5 work with.

6 Several of our declarants make the point  
 7 that off-label use is a big -- a big advantage. Ease  
 8 of recruitment of patients is an advantage of having  
 9 a -- an FDA-approved device.

10 Ease of getting insurance reimbursement  
 11 without which some patients couldn't be treated is --  
 12 is something that's mentioned by Dr. Anderson and also  
 13 by Dr. Sender in his declaration, and also by Mr. Wida.

14 The ease of getting new IDE's approved, if  
 15 your device has already been found safe and effective  
 16 for one application, is quite significant. I think  
 17 eight or nine of our clinician declarants have remarked  
 18 on the fact that it's easier to get IDE's approved in  
 19 your institutional review board and your hospital,  
 20 university, and also by the FDA, if you can say this has  
 21 been found safe and effective by the FDA for at least  
 22 this one application.

23 So the point of all this, and I think Mr.  
 24 Ware has gotten -- fairly gotten into it by this  
 25 letter -- the point of it is that you just can't -- it

1 is unrealistic to think, it is totally impractical to  
 2 think, that if CellPro remained frozen at the number of  
 3 devices and places in the United States as of March  
 4 12th, that Baxter, with no FDA approval, could go in  
 5 there and completely fill the market.

6 It can't. It cannot sell its device  
 7 commercially. It cannot advertise its device. And IDE's  
 8 are not -- they are not a stopgap for commercial sales.  
 9 I think Mr. Wida's declaration makes that very, very  
 10 clear. There would be a shortfall in filling the needs  
 11 of patients for care if -- if CellPro were frozen at  
 12 the number of devices it's now got in place.

13 MR. WARE: There's just a couple of brief  
 14 points.

15 CellPro actually provided us no data at all  
 16 about the number of sites they were in. And I think  
 17 that it is entirely conjecture on the part of Mr.  
 18 Reilly's part that those sites cannot somehow fill the  
 19 needs for patient care.

20 Bone marrow transplants aren't performed in  
 21 every little local hospital. They are performed in  
 22 transplant centers. And it's not clear to me that there  
 23 are even a whole lot more transplant centers in the  
 24 United States, which is one reason I think there was  
 25 essentially no comment on this issue in CellPro's

1 briefing. I don't think that's a real issue, as far as  
 2 the commercial sales.

3 And as far as everything else that CellPro  
 4 is talking about, they are talking about their own uses  
 5 of their product under IDE's, not under approved  
 6 usage -- uses, and in areas where the -- the FDA has  
 7 not concluded that CellPro's device is safe and effective  
 8 for use.

9 So I think we're just, you know, we're  
 10 talking about IDE situations that -- I mean, that's  
 11 what we're talking about when we're talking about the  
 12 stay. This off-label use is -- I think our point is this  
 13 is not something -- this is not a basis on which the  
 14 Court should tailor the stay of the injunction in order  
 15 to specially encourage off-label use of CellPro's  
 16 product, because it's something that, while the FDA may  
 17 not have the authority to regulate on individual doctors'  
 18 use of it, it certainly does disapprove of it, and that's  
 19 not a good basis for an injunction or a stay of an  
 20 injunction, to encourage that.

21 THE COURT: Stop just for a minute. I need  
 22 to take a break or stop.

23 How much longer do you think you'll be?  
 24 MR. WARE: Very short. I think, really, the  
 25 last thing that I wanted to address very shortly was

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1 just the incremental profit point.

2 THE COURT: All right. Why don't we talk  
 3 about that real quick, then I'm going to need to go.

4 MR. WARE: Okay.

5 THE COURT: If anybody has to say anything  
 6 they want to say, feel free to write me.

7 MR. WARE: I think, first of all, just  
 8 conceptually, it's important to underscore our point  
 9 here, which is that anything other than payment to the  
 10 plaintiffs of incremental profit allows CellPro to  
 11 benefit from its willful infringement, and we don't  
 12 think that should be permitted.

13 So I think what the -- so I think the  
 14 concept is entirely appropriate, and I have not really  
 15 heard much argument from CellPro as to why it isn't.

16 What we're mostly arguing about here is the  
 17 floor that we proposed simply to avoid all of the kinds  
 18 of -- all of the kinds of accounting games that can be  
 19 played once you give somebody the ability to calculate  
 20 their incremental profit.

21 And I am sure CellPro would, if we had no  
 22 floor at all, it's quite clear from Mr. Simpson's  
 23 affidavit, that they would say we lose money on every  
 24 sale but I guess hope to make it up with the volume.

25 And I think beyond that, what I'd like to

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1 do is -- do you want very briefly -- there are just a  
 2 couple -- there are a few things that we just picked up  
 3 that are I think just worth mentioning, although if the  
 4 Court prefer that we do it by letter, we can. But they  
 5 have to do with the calculations that Mr. Simpson did.  
 6 And I think we can show the Court why those calculations  
 7 are so off base that they should not be considered at  
 8 all as a basis for establishing a floor for this -- for  
 9 this incremental profit calculation.

10 But if the Court would prefer that we do that  
 11 in writing, we can do that.

12 THE COURT: Realistically, what will happen is  
 13 I will go back and reread the transcript of what was said,  
 14 when I've got Simpson in mind and exactly what went on  
 15 with it. It may be just as easy for you to read the  
 16 letter. I've got another argument coming up at 2:00  
 17 that I need to get focused on.

18 So if you don't mind, I'm happy to have you  
 19 write a supplemental paper, if you don't mind. I'd just  
 20 as soon get it done that way, if that's all right.

21 MR. WARE: Yes.

22 THE COURT: I saw you all carrying a disk  
 23 around. I take it that's probably a disk of the order  
 24 of the form of injunction?

25 MR. WARE: Would that be helpful?

1 conversations with Mr. Culver, who is the CFO of -- the  
 2 CFO of CellPro.

3 Now, if we, so to speak, criticize the  
 4 Simpson declaration, which it is very -- incidentally,  
 5 very easy to do, then they will come back. They'll  
 6 play around with the figures again. We still won't have  
 7 the figures that they are relying on.

8 The only point we are trying to make, your  
 9 Honor, is -- in that letter -- and it's already addressed  
 10 in part in Dr. Hausman's declaration, which had to be  
 11 prepared. We only got their papers last week. Is that  
 12 the figures are not trustworthy because they are very  
 13 selective.

14 For example, they are loading an entire  
 15 year's worth of manufacturing costs and selling costs  
 16 into a year when they only had partial revenues in the  
 17 U.S.. They're comparing apples and oranges.

18 They're also loading the entire costs of  
 19 making all 12.8 profits, including the big devices  
 20 themselves, on to the cost of the disposable units.  
 21 But these are issues we can point out. Simply to say  
 22 the Court shouldn't rely on them, but I don't think  
 23 they should now be offered an opportunity, so to speak,  
 24 to fix what Mr. Simpson has done while still depriving  
 25 us of the information on which he is relying.

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1 THE COURT: There's no harm in passing it  
 2 up.

3 MR. BLOOMBERG: I have two very brief  
 4 points, your Honor, one with respect to misuse.

5 THE COURT: Sure.

6 MR. BLOOMBERG: Will we be allowed to take  
 7 discovery on that topic, your Honor?

8 THE COURT: I think what I am going to do is  
 9 have plaintiffs file their motion for summary judgment,  
 10 stay discovery on it, and then during the briefing, if  
 11 you can identify for me what facts you believe you  
 12 would obtain during discovery as you would under Rule 56,  
 13 in any event. And then we'll see where we are.

14 MR. BLOOMBERG: Fine.

15 And the last point, once we see the letter  
 16 that they are submitting with respect to Mr. Simpson, may  
 17 we file some response if we think it's appropriate?

18 MR. ELLIS: Your Honor, I don't think that's  
 19 quite fair, because they elected to file Mr. Simpson's  
 20 declaration without disclosing the documents from which  
 21 Mr. Simpson extrapolated his data.

22 Mr. Simpson's declaration is arrangement of  
 23 figures that are taken from what is described as  
 24 unaudited financial statements of CellPro that have not  
 25 been provided to us. And based on undisclosed hearsay

1 THE COURT: All right.

2 MR. REILLY: Your Honor, I think what  
 3 probably would be appropriate would be some discovery on  
 4 the question of whether the injunction -- and if it were  
 5 not stayed, would bust CellPro. I think the issue is  
 6 actually broader than that.

7 There was nothing stealth or sneaky about  
 8 Mr. Simpson's declaration. The reason why it had to be  
 9 put together on such short notice is that this \$2,000  
 10 per unit figure that the plaintiffs came up with and  
 11 put in their proposed injunction was something never  
 12 mentioned at trial, never put in the pretrial order,  
 13 and seemed to be kind of picked out of the air.

14 And I think, really, there's a broader issue  
 15 here as to whether the terms of the injunction would  
 16 shut down CellPro. And it goes beyond the \$2,000 per  
 17 item. And I would think if we're going to go any  
 18 farther with this, there probably ought to be a hearing  
 19 on the economic impact. And you cannot really talk  
 20 about that until you know what the scope of the  
 21 injunction is going to be.

22 MR. WARE: Well, our view is that that  
 23 hearing was today, and we are not inclined to continue  
 24 this indefinitely. We've made a suggestion to the  
 25 Court. They've had their chance to respond to it. We

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1 hope that the Court will take our views into 2 consideration and we're anxious to have the Court 3 resolve the issue.	1 (Court recessed at 12:37 p.m.) 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
4 THE COURT: Well, back to the question, if 5 you all are going to submit a paper on Simpson, then 6 they can respond.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
7 If you are not going to submit something, 8 then I will just let the record sit the way it is, 9 unless somebody tries to lob something in.	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
10 MR. WARE: Then let me say this: I think 11 that Dr. Hausman's affidavit adequately sets out our 12 points, if I can add one more simply, which is that as 13 we looked at their all calculations today, this morning, 14 what we saw is that when they calculated the per-unit 15 costs of the disposables, they did it based on sales, 16 or based on manufacturing something like 4600 units. 17 They actually sold and compared it to about 18 2300 units. So they figured out the cost of making and 19 building an inventory for twice the number of product 20 that they actually sold and then they said that that is 21 the per-unit cost that should be considered.	10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
22 So that's one point we wanted to add to what 23 we said before. But, unless I'm mistaken, I'll speak with 24 Mr. Ellis. I think probably we were going to underscore 25 points that are in Dr. Hausman's affidavit and it's	22 23 24 25
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1 probably not necessary to go into it further.	
2 THE COURT: Well, actually, what I was also 3 going to say is it may not be something that anybody 4 wants to hear. I see the injunction as an equitable 5 remedy and a remedy where I have to try to get it right. 6 And if somebody shows me today, next year, two years from 7 now that it's not right, I may have to keep tinkering 8 with it and until I do it.	
9 And if it means I enter an injunction that 10 misses the target a little bit and I go back and re-do 11 it later, I'll go back and re-do it later. And I may 12 appoint somebody to go back out and give me some 13 accurate numbers and have them do it.	
14 But we'll see.	
15 MR. WARE: Thank you very much, your Honor.	
16 THE COURT: All right. I think what's going 17 to happen is the next thing I will see is a motion for 18 summary judgment on patent misuse and I will get working 19 on issues on my plate, including enhance -- enhancement 20 of damages, attorneys' fees and nature of the injunction.	
21 And when I receive the briefing on misuse, I 22 take it one of the things I'll see is whether there needs 23 to be evidentiary discovery on this subject or whether I 24 can resolve it without further discovery.	
25 (Counsel respond "Thank you, your Honor.")	

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